UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA,

Plaintiff

vs. **CRIMINAL NO. 5:14-CR-00926**

VASCULAR SOLUTIONS, INC., AND HOWARD C. ROOT,

Defendants.

STIPULATION

The parties, by and through their undersigned counsel, hereby stipulate as follows:

1. In its Answer in a prior lawsuit with the government ("the Lawsuit"), Vascular Solutions, Inc., stated: "VSI admits that its laser device has not received a specific FDA-approved indication for treatment of perforator veins."

2. In Paragraph 34 of the Complaint filed in the Lawsuit, the government alleged:

"34. In order to compete with RF, Vascular Solutions knew it had to offer a system that matched, procedure for procedure, what RF offered. One place Vascular Solutions could not match RF was in perforator ablation. VNUS had a perforator indication for its RF device, but Vascular Solutions did not. If Vascular Solutions could not match RF by procedure, the company believed it would be harder to sell its consoles."

3. Vascular Solutions responded to the allegation in Paragraph 34 as follows:

"VSI admits that VNUS had a perforator indication for its RF device and that VSI did not have a perforator indication for its laser device during the time period relevant to the Complaint. VSI denies the remaining allegations in paragraph 34."

4. In Paragraph 39 of the Complaint filed in the Lawsuit, the government alleged:

"At no time has any Vascular Solutions product been indicated for the treatment of perforator veins."

5. Vascular Solutions responded to the allegation in Paragraph 39 as follows:

"VSI admits that it has never received a specific indication for the treatment of perforator veins in its 510(k) clearances. VSI denies the remaining allegations in Paragraph 39."

6. During the Lawsuit, the government asked Vascular Solutions the following question in a legal document called "United States' First Set of Interrogatories":

"State the basis for Vascular Solutions' decision to seek 510(k) clearance, on or about June 29, 2007, for the Short Kit. Your response shall identify all documents and witnesses related to the decision to file the 510(k) application."

7. Vascular Solutions responded to this question as follows:

"VSI objects to this Interrogatory as vague. Subject to the foregoing objection, VSI believed at the time that the existing indication for use for the Vari-Lase endovenous laser therapy kits applied to the treatment of perforator veins as well as treatment of the great saphenous vein and other veins in the lower extremity. VSI filed the 510(k) application in an attempt to confirm with the FDA this interpretation before promoting the Short Kit for use in perforator veins in the United States. See documents VS001471-1484, VS189762-VS189872, and VS189909-VS189939. Howard Root and Deborah Schmalz (formerly Neymark) have knowledge of the basis for VSI's decision to seek 510(k) clearance for the Short Kit."

Dated: February 22, 2016

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